

Cleaning and Disinfection Protocol

Cleaning & Disinfection Protocol for Cleanrooms

This document has been developed in accordance with the current applicable USP <797> guideline. It is intended for use as a guideline only. At no time should this document replace existing documents established by the facility unless written permission has been obtained from the responsible facility manager.

PREFACE

Even if a cleanroom's primary and secondary engineering controls are sufficient and if strict garbing, hand-washing, and particulate-control measures are put in place, consistent and effective cleaning procedures are still required to continually minimize the overall bioburden present in the facility.

This guideline is an overview of the cleaning and disinfection guidelines for ISO Class 5 to 8 cleanrooms. Cleanrooms are classified by how clean the air is. For example, ISO Class 5 rooms would be the cleanest, and ISO Class 8 rooms would be the dirtiest. According to Federal standards, the number of particles equal to and greater than 0.5mm is measured in one cubic foot of air, and this count is used to classify the cleanroom.

Class	Max particle/m ³ (≥0.1 um)	Max particle/m ³ (≥0.2 um)	Max particle/m ³ (≥0.3 um)	Max particle/m ³ (≥0.5 um)	Max particle/m ³ (≥1 um)	Max particle/m ³ (≥0.5um)
ISO 5	100,000	23,7000	102,000	35,200	8,320	293
ISO 6	1,000,000	237,000	102,000	35,200	8,320	2,930
ISO 7	-	-	-	352,000	83,200	2,930
ISO 8	-	-	-	35,200,000	8,320,000	293,000

PREPARATION

Cleaning and maintenance of cleanrooms prevents the build-up of soils, dust and other foreign material that can harbour pathogens and support their growth. Daily cleaning and disinfection of environmental surfaces and equipment are important in limiting the transmission of organisms.

Appropriate personal protection should be taken for those responsible for the decontamination of a cleanroom.



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PROTECTIVE BARRIERS

Appropriate personal protection should be taken for those responsible for the decontamination of a cleanroom.

1. Disposable gloves
2. Lint free shoe covers
3. Bouffant caps
4. Surgical masks
5. Safety glasses
6. Gowns or frocks
7. Beard covers (if needed)

PRODUCTS

All disinfectant or disinfect-cleaner products to be used for cleaning and disinfection of a cleanroom must be approved by either the U.S. Environmental Protection Agency (EPA) or Health Canada and carry an EPA number or Drug Identification Number (DIN). Products claiming to be a disinfectant but do not carry an EPA number/DIN have not been approved for sale in the US or Canada and should not be used. The products used for cleaning and disinfecting are to be chosen with careful consideration of effectiveness, safety and compatibility. Ideally, a disinfectant technology should display broad spectrum microbicidal efficacy, display good cleaning efficacy, be safe to use, be environmentally sustainable and have widespread material compatibility.

Disinfectant Chemistries Approved for Disinfection of Cleanrooms:

1. Accelerated Hydrogen Peroxide® (AHP®)
2. Sodium Hypochlorite
3. Isopropyl Alcohol
4. Quaternary Ammonium Compounds (QUATs)
5. Phenols
6. Iodophors

The concentration and contact time for each product will differ. For that reason it is important to read the product label prior to commencing any cleaning and disinfection process. Some chemistries such as QUATs and Phenols leave behind active residues which can contribute to resistant microflora by allowing bacteria to build up resistance. If using these kinds of chemistries, the development of resistant microflora can be prevented by rotating cleaning agents.



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RECOMMENDED PROCEDURES FOR PREPARING CLEANING SOLUTIONS

It is imperative that the cleaning-agent manufacturer's instructions be followed with regard to storage, handling, and dilution. Safety Data Sheets (SDS) are readily available from solution manufacturers and must be available on site.

- Solutions must be diluted and mixed immediately prior to use, and documentation of their preparation is strongly recommended. The use of automated dilution systems is recommended to ensure the proper concentration of active is measured. Test strips, if available, are also recommended to ensure required concentration of active.
- If the use of an automated dilution system is not possible, make glass or plastic graduated cylinders available at the sink where solutions are mixed and thoroughly rinse them after.
- Sterile water for irrigation is used with the appropriate cleaning agent in any ISO Class 5 area, including work bench or hood surfaces, walls or other surfaces of the area, and any compounding equipment.
- Sterile water for irrigation should also be used for intermittent hand decontamination
- Ensure that Spray-bottle solutions are changed in accordance with manufacturer's instructions for the shelf life of the product once diluted. Prepared solutions should be labeled with their expiry dates, and kept immediately outside the ISO Class 5 area for use in re-sanitizing hands prior to re-entry.
- Tap water may be used with the appropriate cleaning agent for all other surfaces, including walls, ceilings, production/storage bins, cleanroom-grade-steel furniture and exterior surfaces of the work bench or hood.

RECOMMENDED PROCEDURES FOR CLEANING EQUIPMENT AND SUPPLIES

Appropriate cleaning equipment and supplies should be used for the cleaning and decontamination of a cleanroom.

- Buckets and other cleaning equipment, such as mop handles, heads, and covers, must be dedicated to the area where they are used.
- To prevent cross-contamination, equipment used to clean walls and ceilings should not be used to clean floors, nor should they be taken outside of the pharmacy area.
- Equipment to clean an ISO Class 6 or 7 area should not be used to clean an ISO Class 8 area.
- Conventional mops with cellulose heads should be changed every 48 hours to prevent shedding, and conventional mop handles should be replaced every month.
- Buckets must be metal free and made of heavy-duty plastic.
- Low-lint (low particle generation) cleaning tools made from synthetic microfibers should be used in ISO class 5 to 8 areas. Larger wipes are generally preferred as they cover more surface



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area.

- Low-lint wipes dipped in the diluted cleaning agent can be used to clean work benches and hoods and to wipe molding, doors, handles, furniture, product storage bins, as well as to wipe products before they enter the cleanroom and to dry hands.

RECOMMENDED PROCEDURES FOR CLEANING AND DISINFECTION

Cleaning and disinfection should generally occur from the cleanest area to the dirtiest – from an ISO Class 6 or 7 cleanroom to the ISO Class 8 anteroom. Generally cleaning and disinfection should be done from top to bottom. Daily cleanings should be performed at the end of the compounding day. For ISO Class 5 cleanrooms, workstation surfaces should be wiped with the designated agent at the beginning of each compounding day. It is important to make certain that all surfaces are thoroughly coated and wetted with the cleaning and disinfectant agent.

Daily Cleaning Checklist

- Empty waste receptacles and replace liners (daily or as often as needed)
- Remove hazardous-waste receptacles
- Remove biohazardous materials
- Clean ISO Class 5 workstations (including compounders residing in the workstations)
- Clean sinks, countertops, cart tops, stool tops, and exterior of sharps containers
- Mop floors

Weekly Cleaning Checklist

- Empty waste receptacles and replace liners (daily or as often as needed)
- Remove hazardous-waste receptacles
- Remove biohazardous materials
- Clean ISO Class 5 workstations (including compounders residing in the workstations)
- Clean sinks, countertops, cart tops, stool tops, and exterior of sharps containers
- Mop floors
- Clean windows, walls, and all other horizontal surfaces, including doors and side, front, and back of hoods, from top to bottom
- Empty, clean and sanitize storage shelving and bins
- Clean and sanitize any other non-compounding furniture such as carts, stools, and waste containers

Monthly Cleanings Checklist

- Empty waste receptacles and replace liners (daily or as often as needed)
- Remove hazardous-waste receptacles
- Remove biohazardous materials
- Clean ISO Class 5 workstations (including compounders residing in the workstations)
- Clean sinks, countertops, cart tops, stool tops, and exterior of sharps containers



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- Mop floors
- Clean windows, walls, and all other horizontal surfaces, including doors and side, front, and back of hoods, from top to bottom
- Empty, clean and sanitize storage shelving and bins
- Clean and sanitize any other non-compounding furniture such as carts, stools, and waste containers
- Clean and sanitize interior and exterior of refrigerators and incubators (not kept in controlled environments)
- Clean ceilings of all controlled environments

RECOMMENDED CLEANING AND DISINFECTING PROCEDURES FOR DRUG SPILL

In the event of a drug spill, wipe the spill with sterile water if in the ISO Class 5 area, or with tap water, using a lint free wipe, followed by the designated cleaning agent. This process will avoid the occurrence of chemical reactions between pharmaceutical components and cleaning agents.

REFERENCES

U.S. Pharmacopeial Convention. General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. September, 2015.

Douglas, Kate. Establishing Sound Practices for Cleaning Your Cleanroom: Cleaning Products and Procedures for <797> Compliance.

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